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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,737	07/31/2003	Ping Gao	01261/2/US	3875

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,737	GAO ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-30 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-30, drawn to dosage forms comprising a fill material in capsule shells, wherein the fill material comprises a selective COX-2 inhibitor drug and a pharmaceutically acceptable sulfite compound, wherein the COX-2 drug is described by formula (1) in claim 21 having A = pyrazolyl, classified in class 514, subclass 403 (based upon the active agent).

II. Claims 1-22 and 25-30, drawn to Claims 1-30, drawn to dosage forms comprising a fill material in capsule shells, wherein the fill material comprises a selective COX-2 inhibitor drug and a pharmaceutically acceptable sulfite compound, wherein the COX-2 drug is described by formula (1) in claim 21 having A = furanyl, classified in class 514, subclass 183 (based upon the active agent).

III. Claims 1-22 and 25-30, drawn to Claims 1-30, drawn to dosage forms comprising a fill material in capsule shells, wherein the fill material comprises a selective COX-2 inhibitor drug and a pharmaceutically acceptable sulfite compound, wherein the COX-2 drug is described by formula (1) in claim 21 having A = pyridinyl, classified in class 514, subclass 277 (based upon the active agent).

IV. Claims 1-22 and 25-30, drawn to Claims 1-30, drawn to dosage forms comprising a fill material in capsule shells, wherein the fill material comprises a selective COX-2 inhibitor drug and a pharmaceutically acceptable sulfite compound,

wherein the COX-2 drug is described by formula (1) in claim 21 having A = isoxazolyl, classified in class 514, subclass 183 (based upon the active agent).

V. Claims 1-22 and 25-30, drawn to Claims 1-30, drawn to dosage forms comprising a fill material in capsule shells, wherein the fill material comprises a selective COX-2 inhibitor drug and a pharmaceutically acceptable sulfite compound, wherein the COX-2 drug is described by formula (1) in claim 21 having A = cyclopentenoyl, classified in class 514, subclass 690 (based upon the active agent).

IV. Claims 1-22 and 25-30, drawn to Claims 1-30, drawn to dosage forms comprising a fill material in capsule shells, wherein the fill material comprises a selective COX-2 inhibitor drug and a pharmaceutically acceptable sulfite compound, wherein the COX-2 drug is described by formula (1) in claim 21 having A = pyridazinonyl, classified in class 514, subclass 247 (based upon the active agent).

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions, modes of operation. These compounds represent different structural sub-genus, wherein the genus is characterized solely by its function (i.e. inhibition of COX-2). Although these compounds share a phenylsulfonamide moiety, the core of each compound varies considerably as evidenced by the different heterocyclic species possible for A. For this reason, it is expected that these compounds would have significantly different interactions with COX-2 receptor active sites.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper. The prosecution of parent case 10/119,129, wherein the previous Examiner cited Talley et al., supports this conclusion (U.S. Patent No. 5,760,068). Talley et al. only teaches compositions where A = pyrazinyl. Therefore, a search of the prior art for all possible permutations of Applicants' claimed COX-2 inhibitors would represent an undue burden upon the examiner. **A complete response will include a chemical structure of the compound corresponding to the elected group, wherein a single value for the A-substituent, as well as all other variable substituents, are clearly defined and set forth. In other words, the Examiner is requesting *the election of a single compound of formula (1) recited in claim 21*.**

Additional Species Election

Claims 1, 9, 17, and 20 are generic to the following disclosed patentably distinct species: (a) sulfite compounds (claim 1); (b) additional excipient classes (claim 1); (c) surfactants (claim 9); (d) solvent (claim 17); (e) cosolvent (claim 20); (f) capsule shell type (claim 1); and (g) fill material form (claim 1). The species are independent or distinct because these species represent different classes of excipient compounds (species (a)-(e)), capsule shell types (f), and physical forms (g) and a search for one particular excipient or shell type or physical form is not expected to uncover the other excipient classes, shell types, or physical form. Applicant is respectfully

requested, for initial examination purposes only, to elect **a single disclosed species**, **for each item (a)-(g)** described above.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species, which depend from or otherwise require all the limitations of an allowable generic claim. If claims are added after the election, Applicant is respectfully requested to indicate which are readable upon the elected species.

A telephone call requesting an oral election was not made due to the complexity of the instant restriction/species election. It is proper for the Examiner to send a written restriction/election requirement whenever said restriction/election is deemed complex (See MPEP § 812.01).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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